

RECEIVED
CENTRAL FAX CENTER

Remarks

OCT 10 2006

I. Support For The Amendment

The Title has been amended to reflect the claimed subject matter more clearly.

Support for the amendment of Claim 7 is found in the Specification at page 10, line 11; and in original Claim 15.

Claim 9 has been amended to correct the pendency, such that claim 9 now depends from Claim 7.

No new matter has been added by these amendments.

II. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 9, 18, 24 and 30 stand rejected as allegedly indefinite. Applicants respectfully traverse these rejections.

Claim 9 depends from cancelled Claim 8. Claim 9 has been amended to depend from pending Claim 7. Applicants respectfully request that this rejection be reconsidered withdrawn.

In Claim 18, the Examiner objects to the term "antibody half molecule." However, the Examiner has not established *why* one of ordinary skill in the art would not have understood what this term means. At any rate, at page 20 of the Specification, last line, to page 21, first line, Applicants refer to this term and reference U.S. Patent No. 4,470,925 ("the '925 patent"). At column 1 of the '925 patent, lines 26-27, the term "antibody half molecule" is discussed and refers to a structure that contains one antibody heavy chain and one antibody light chain. Thus, one of ordinary skill in the art would have understood what this term means.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

The Examiner also objects to the term "unit dose" in claims 24 and 30. Applicants respectfully traverse this rejection. However, the Examiner has not established *why* one of ordinary skill in the art would not have understood what this term means. At any rate, one of ordinary skill in the art would have understood that in a unit dose, medication is dispensed in a package that is ready to administer to a patient. Moreover, as shown in the attached MicroPatent search report cover page,

the term "unit dose" is recited in the claims of hundreds of patents that issued prior to the December 29, 1999 international filing date of the application to which the present application claims priority. If the term were unclear, why would the United States Patent and Trademark office grant patents with claims that recite that term?

Applicants respectfully request that this rejection be reconsidered and withdrawn.

III. The Rejection Under 35 U.S.C. § 102 Should Be Withdrawn

Claims 7, 9 and 17-30 stand rejected as allegedly anticipated by Adema¹. The Examiner relies on Bost² and Bendayan³, to allegedly show that antibody binding of distinct proteins was specific. Applicants respectfully traverse this rejection.

Claim 7 has been amended to recite a purified antibody or fragment thereof which specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 6, wherein when the antibody or fragment thereof is contacted with a sample suspected to contain the polypeptide of SEQ ID NO: 6 under conditions in which a stable antigen-antibody complex can form between the antibody or fragment thereof and the polypeptide in the sample, any antigen-antibody complex formation is detected, wherein detection of an antigen-antibody complex indicates the presence of the polypeptide of SEQ ID NO: 6 in the sample.

In Claim 7, as amended, the recited antibody or fragment thereof specifically binds the polypeptide of SEQ ID NO: 6, but does not specifically bind other antigens. That is because if an antigen-antibody complex formation is detected, it must be the polypeptide of SEQ ID NO: 6 that is specifically bound by the antibody or fragment thereof. Thus, binding of by the claimed antibody or fragment thereof to the polypeptide disclosed in Adema is excluded.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

¹ Adema *et al.*, publication no. WO 98/24906.

² Bost, K.L. and Pascual, D.W., *Immunological Investigations* 17(6&7): 577-586 (1988).

³ Bendayan, M., *J. Histochemistry and Cytochemistry* 43(9): 881-886 (1995).

It is believed that each of the Examiner's objections and rejections have been addressed herein.

Respectfully submitted,



Grant E. Reed
Attorney for Applicants
Reg. No. 41,264

Schering-Plough Corporation
Patent Department
Mail Stop K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Telephone No. (908) 298-5067
Facsimile No. (908) 298-5388

**MicroPatent® PatSearch FullText: Patent List
Record Browsing and Document Delivery**

Search scope: US Granted; Claims
Years: 1971-2006
Text: "unit dose" Issue/Publication Date: <19991229

939 patents. This page: 1 - 50 (Unsorted)

[Order/Download](#)

[Find Similar](#)

[\[Choose an action\]](#)

[Go](#)

[Worksheet](#)

For additional processing options (graphs, sorting, reports), go to

[Search History](#)

Highlight the search terms in the full-text record

[New](#) [Last](#) [Help](#)

Check All Uncheck All

1. [US60009128A](#) A61K 19991228 Hoffman-La Roche Inc.

Pharmaceutical compositions containing proteinase Inhibitors

2. [US6000916A](#) A45D 19991228 Color Prelude, Inc.

Cosmetic sampler with applicator backing

3. [US6000983A](#) C07D 19991221 Novo Nordisk A/S

N-substituted azaheterocyclic compounds

4. [US6000456A](#) C07K 19991221 Baxter Aktiengesellschaft

High level expression of polypeptide that contains modified preS1 region of hepatitis B virus large antigen

<http://www.micropat.com/perl/pshillist/display.pl?listid=92877200609141952&ticket=793364344185>

09/14/2006